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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,341	03/20/2001	Kathy L. Miller	P1780R1	1230

7590 10/17/2002  
Attn: Wendy M. Lee  
1 DNA Way  
South San Francisco, CA 94080-4990

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/813,341

Applicant(s)

MILLER ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 July 2002 and 20 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 17-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15, 17-80 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The instant application has been transferred to this examiner. This examiner notes applicant elected group I without traverse in Paper No. 9, in response to the Office Action mailed on 07/02/2002, Paper No. 8, however, there are multiple inventions in the elected group, which would put serious burden on the examiner. Therefore the Office Action, Paper No. 8 is vacated and replaced by the following new Election/Restrictions Requirement.

Claims 1-15, 17-80 are pending and subjected to Election/Restrictions.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-15, 17, 18, 20-28, 30-48, and 50-80 link(s) inventions I-XIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-15, 17, 18, 20-28, 30-48, and 50-80. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- I. Claims 1-15, 17-20, 43-49, 56-68, 71-80, drawn to antibody to Her-2 and conjugated Her-2 to a cytotoxic agent, classified in class 530, subclass 387.1.

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- II. Claims 1-15, 17, 18, 20, 43-48, 56-68, 71-80, drawn to antibody to EGFR, and the conjugated antibody to cytotoxic agent, classified in class 530, subclass 387.1.
- III. Claims 1-15, 17, 18, 20, 43-48, 56-68, 71-80, drawn to antibody to Her-3, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.
- IV. Claims 1-15, 17, 18, 20, 43-48, 56-68, 71-80, drawn to antibody to Her-4, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.
- V. Claims 1-15, 17, 18, 20, 43-48, 56-68, 71-80, drawn to antibody to DCR3, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.
- VI. Claims 1-15, 21-26, 33-42, 57-69, 73-80, drawn to antibody to DR4, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.
- VII. Claims 1-15, 21-26, 33-42, 57-69, 73-80, drawn to antibody to DR5, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.
- VIII. Claims 1-15, 21-23, 25, 33-39, 41, 42, 57-69, 73-80, drawn to antibody to DCR1, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.
- IX. Claims 1-15, 21-23, 25, 33-39, 41, 42, 57-69, 73-80, drawn to antibody to DCR2, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.
- X. Claims 1-15, 27-29, 50-55, 57-68, 70, 73-80, drawn to antibody to CD20, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.
- XI. Claims 1-15, 27-28, 50-55, 57-68, 70, 73-80, drawn to antibody to CD19, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.

- XII. Claims 1-15, 27-28, 50-55, 57-68, 70, 73-80, drawn to antibody to CD22, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.
- XIII. Claims 1-15, 27-28, 50-55, 57-68, 70, 73-80, drawn to antibody to CD40, and the conjugated antibody to cytotoxic agent classified in class 530, subclass 387.1.

Inventions I-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different products with different chemical structures and different biological activities.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. The search required for each of the above inventions is not coextensive with regard to the literature and the sequence searches. Further, a reference which would anticipate the invention of any one group would not necessarily anticipate or make obvious the any of the other groups. For these reasons, restriction for examination purposes is proper.

All of the groups 1-XIII above contain claims generic to a plurality of disclosed patentably distinct species. Virtually unlimited number of different structures of antibodies could be constructed by different combinations of the variables. Groups 1-XIII contain three different genres of species:

- 1) The different number of binding sites (claims 1-4, 50-54, 56).
- 2) The different structures in VDs, number of amino acids in X positions, VH and CH linking patterns (claims 5-10, 57-68, 73-79).
- 3) The specific amino acids sequences of linkers (claims 11).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the three different genres for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-11, 50-54, 56-68, and 73-79 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu  
October 13, 2002

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
1600